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December 20, 2005

To: Virginia EMS Agencies
Regional EMS Councils
Operational Medical Directors

From: Michael D. Berg
Manager, Regulation and Compliance

Subject: Virginia Board of Pharmacy and Transfilling of Oxygen

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After talking with FDA, the Board of Pharmacy is adjusting their previous guidance (November 15, 2005) about licensure being required in order for EMS agencies to transfill their own oxygen. The following is an excerpt from an FDA guidance document called Fresh Air 2000 which can be found at http://www.fda.gov/cder/dmpq/freshair.htm. FDA stresses that this is guidance and not law or rule. The Board of Pharmacy follows FDA guidance as to whether an activity constitutes manufacturing. Because it does not appear the FDA will require registration by EMS agencies under the specific circumstances below, then the Board of Pharmacy will not require it either. However, if all of the conditions below are not met, then the agency will have to register with FDA and with the Board of Pharmacy and meet all requirements for gas repackaging.

Excerpt from "Fresh Air 2000", FDA guidance EMERGENCY MEDICAL SERVICES (EMS)

“EMS, i.e., fire departments, ambulance companies, rescue squads, etc. are defined as the following:

1) They are usually state government affiliated emergency services,

2) They transfill Oxygen U.S.P. for their own use only. No other gases may be filled on site,

3) They administer Oxygen U.S.P. to patients, victims, etc. in an emergency situation, and

4) They charge no specific fee for the administration of Oxygen U.S.P. nor do they receive any reimbursement from Medicare or Medicaid.

At the current time, we are not requiring EMS to register or list with FDA as long as the following minimum requirements are implemented: a) establish written procedures covering all operations including distribution within the organization, recalls, labeling, training, etc.; and b) establish records documenting the above. For specific details, please refer to the previously discussed sections of the CGMPs (current good manufacturing practice).

CAUTION: Any EMS failing to comply with (a) and (b) above, would be subject to the full CGMP requirements and would be required to register and list with the agency according to the FDA's defintiion, and will be inspected."

Additional questions regarding this notification can be forwarded to the Division of Regulation and Compliance by calling 804-864-7600 or to the Board of Pharmacy by either calling 804-662-9911 or email pharmbd@dhp.virginia.gov.